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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

**IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION**

THIS DOCUMENT RELATES TO:

Hannah v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10407;

Jones v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10409;

Ramos v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10410;

Rios v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10411;

Rivera v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10412;

Tayvinsky New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10414;

Gould v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10444; and

Normand v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10447

MDL No. 1:13-md-2419-FDS

**RESPONSE TO PLAINTIFFS' STEERING
COMMITTEE'S OPPOSITION TO OUR MOTION
TO DISMISS PURSUANT TO F.R.C.P. 12(b) (6) ON
BEHALF OF DEFENDANTS, PREMIER
ORTHOPAEDIC and SPORTS MEDICINE
ASSOCIATES OF SOUTHERN NEW JERSEY,
LLC, trading as PREMIER ORTHOPAEDIC
ASSOCIATES, PREMIER ORTHOPAEDIC
ASSOCIATES SURGICAL CENTER, LLC, and
KIMBERLEY YVETTE SMITH, M.D. a/k/a
KIMBERLEY YVETTE SMITH-MARTIN, M.D.**

INTRODUCTION

As Your Honor is aware, the Premier Defendants have filed a motion to dismiss pursuant to F.R.C.P. 12(b)(6) in the above referenced matter. The Plaintiffs' Steering Committee (PSC) has filed an opposition to this motion. Please accept this short legal brief in response to the opposition filed by the PSC. While not all of the responses by the PSC are addressed below, the Premier Defendants maintain the original position set forth in the original papers filed in support of the motion to dismiss. The relief requested originally by the defendants should be granted.

LEGAL ARGUMENT

I. Plaintiff's Negligence Claims Are Subsumed By The New Jersey Products Liability Act.

The plaintiff's argue that the negligence and inform consent cases survive dismissal because they are alleging that defendants breached a duty in the performance of their services, which would survive a motion for dismissal under *Snyder v. Mekhjian*, 582 A.2d 307 (N.J. Super. Ct. App. Div. 1990). This argument however is misplaced. The Court in *Snyder* allowed the plaintiffs to pursue a theory of negligence on an argument that the surgical procedure was performed inappropriately (surgeons failed to control a bleeding artery during surgery requiring a blood transfusion) and a theory of informed consent regarding the risks of obtaining a blood transfusion. However, the Court did dismiss plaintiff's claims that the hospital and other medical providers were responsible for inspecting, and ensuring that the blood products received by Mr. Snyder were in fact safe. Specifically the Court framed plaintiff Snyder's claims as follows:

“Plaintiff claims that since the blood he received from BCBC could have been made safe, all those in the chain of collection and distribution of the infeceted blood he did receive should be held strictly liable for providing him with a defective product.”

Id. at 310. The claims made in *Snyder* regarding the custodian's duty are almost identical to the claims made by the PSC in the case before this Court. The PSC states generally in their pleading

that defendants have an obligation to provide a safe product to their patients. The plaintiffs do not allege a deviation in the actual performance of the steroid injections; the technique of the procedure, angle of insertion, sterility of the procedure and so forth is not being questioned. Therefore the only negligence claim that is being pursued is one of failing to provide a safe product. This claim is subsumed by the New Jersey Product Liability Act despite the holding in *Snyder*. In point of fact, *Snyder* specifically dismissed plaintiff's claims for holding the medical providers responsible for a product that could have been made safe but wasn't, just because they took possession of the product.

The PSC also points to the case of *Johnson v. Mountainside Hospital*, 571 A.2d 318 (N.J. Super. Ct. App. Div. 1990). The appeal in *Johnson* center around many issues, one of which was whether the Hospital was a lessor of equipment, which ultimately failed causing the death of Aurelia Johnson, a patient. Ms. Johnson was attached to a ventilator while in the hospital, however the ventilator was disconnected at one point without the medical providers knowing and she suffered brain injury and ultimately death. The plaintiff brought suit against the maker of the ventilator equipment but that claim was settled before trial. The Trial Court ruled that the hospital could not be held strictly liable to the plaintiff's for their relationship with the medical device company. The Court reiterated the New Jersey Supreme Court's holding in the *Feldman v. Lederle Laboratories*, case in which it was stated:

“When the essential nature of the transaction involves a service rather than a product, public policy may dictate, in view of the status of the provider that the general welfare is served better by inapplicability of the strict liability doctrine. . .”

Feldman v. Lederle Laboratories, 97 N.J. 429, 442 (1984).

The *Johnson* decision was decided seven months before the *Snyder* case. At a time when the Appellate Division in New Jersey was deciding *Snyder* it had an opportunity to clarify and/or

expand the ruling in *Johnson*. However the Court did not do so. It is well settled that when the injury in a case involves a product, the negligence claims of a provider are precluded, except for where the issues involve the performance of the service (i.e. repairing a bleeding artery, surgical technique or use of a ventilator). Where the theory is one that the healthcare providers are responsible for the safety of the product as are alleged here plaintiff's claims for negligence should be dismissed.

II. Plaintiff's Claim For Battery Must Be Dismissed.

Plaintiff responds to defendant's motion by stating that no plaintiff consented to being injected with “. . . mail ordered medication from an unaccredited, non FDA approved compounding pharmacy they never heard of, was located hundreds of miles away and that their doctors and their practice had never visited or otherwise seen.” Respectfully, it can hardly be argued that patients under these circumstances ever understand from which pharmacy or drug manufacturer their drugs are derived. Too, ordering medication through the mail cannot be considered uncommon unless plaintiffs' contend that the circumstance dictates that the medical providers hand deliver their orders and personally pick up the medication when it is ready. In fact, plaintiffs do not make such an allegation. Finally, but importantly, there is no serious allegation by the plaintiffs against the Premier Defendants that they actually knew the steroids were contaminated and injected the medication into the patient. There simply is not factual basis pled in the complaint that Premier had actual knowledge of contamination and with that knowledge still decided to inject the patients with a contaminated product.

There is no dispute that the patients in this case consented to an epidural steroid injection. The medication injected was a steroid. This is distinguishable from the case of *Murphy v. Implicito* cited by the PSC. In *Murphy* a physician inserted cadaver bone during a procedure where previously an “iliac crest bone graft”. The patient in *Murphy* received, with the doctor's

knowledge, a totally different product. In fact, inserting a foreign material (cadaver bone) into a patient without their consent may be a battery. However, if they took the bone graft from a different part of the body, it would not be a battery. Here, the patient was told they would have a steroid injection and they received a steroid injection. To make a distinction that the steroid was preservative-free is of no consequence. The preservative itself does not alter the medication, in fact it may make the injection more comfortable for the patient if preservative-free medication is used. Regardless, the fact that preservatives were not present in the medication cannot alone sustain a pleading of battery. The plaintiffs consented to the procedure by the physicians and that procedure was performed with the intended medication being administered. A claim for Battery is therefore not sustainable.

III. Plaintiffs Allegations Of Civil Conspiracy Must Be Dismissed

Plaintiffs argue that there is sufficient evidence to show that NECC entered into an agreement with Premier Orthopedics to defraud the Massachusetts Board of Pharmacy. However, the claim is purely speculative. Plaintiffs provide examples of conduct engaged in by the St. Thomas Defendants and attempt to draw a parallel to the conduct of the Premier Defendants. Plaintiff does not provide any evidence besides the conduct of St. Thomas including their alleged agreement to provide fake names to fulfill a regulatory requirement and a conclusory statement that “the clinic related defendants had similar communications with NECC.” This communication is outlined in plaintiff’s complaint and identified as the “principle” issue in the conspiracy. Specifically, plaintiffs allege in the complaint,

“The Conspiracy principally involved NECC’s request that the Clinic Related Defendants provide patient names for patients the clinic related defendants intended to provide with MPA or other pharmaceuticals. The Clinic Related Defendants, however, could not provide such patient lists and NECC requested the Clinic Related Defendants submit any list of names to be provided to the Board.”

(See plaintiff’s complaint at pg. 340).

In fact, recently Premier served plaintiffs with discovery in response to a subpoena, which included order forms sent to NECC for vials of MPA. These forms listed the actual names of the patients receiving the medication. Furthermore, this discovery was void of any agreement with NECC to provide a list of names to comply with a statute or regulation. No such agreement existed between NECC and this moving defendant. Plaintiffs are attempting to “shoehorn” a claim for civil conspiracy based on facts that may not be true about a defendant in Tennessee (St. Thomas) but that have not been pled sufficiently about the moving defendant. Finally, before plaintiffs filed the Master Complaint in this case they were and still are in possession of informal discovery from NECC.¹ That discovery, likely contains communications with various defendants. This information was known to the PSC before the drafting of the master complaint in this case. Therefore if some agreement had existed it would have likely appeared in the pleadings just as reference was made to that of the St. Thomas Defendants. Therefore, without some evidence of an agreement to defraud the Massachusetts Board of Pharmacy, plaintiffs have failed to prove their claim.

IV. Plaintiff’s Attempt To Evoke An Exception To The Learned Professional Exclusion To The CFA Is Misplaced; Any Claim For Consumer Fraud In This Case Against The Premier Defendants Must Be Dismissed.

Plaintiff argues that Premier was not acting in the scope and course of their profession and that the ordering practices regarding MPA was too far removed from the exercise of the care and skill of a medical professional and that as such the PSC’s claims under the New Jersey Consumer Fraud Act (NJCFRA) have been sufficiently plead. Such is not the case.

¹ The PSC had an agreement to exchange “informal discovery” with NECC. As part of that agreement certain documents maintained by NECC were exchanged with the plaintiffs. This discovery is a mystery to the defendants as it has not been disclosed to the defendants though through information and belief the materials likely include communications with the clinics if any as well as order forms for medications at a minimum.

Premier Orthopedics provided medications to their patients that it had every right to believe were not contaminated. NECC advertised to their customers that it complied with the highest level of regulatory control for compounding pharmacies. In addition, the ordering of preservative free methylprednisolone was to induce a benefit to the patient. Preservatives will often act as an irritant to the patient when injected into the epidural space. Therefore the use of preservative free medication is preferable. This fact alone places the decision to order compounded drugs squarely in the area of exercising professional skill and judgment.

Moreover, the drugs were used during a sterile, surgical procedure in an office setting. Unlike the cases cited by the plaintiffs, this was not part of the “entrepreneurial and business aspect of the medical practice.” The decision regarding what medication to provide to a patient is well within the clinical judgment of a physician and according to the case law cited by both the moving party and the PSC the NJCFA precludes such a cause of action.

As a result of acting within the prevue of their professional capacity, any and all claims alleging a violation of the New Jersey Consumer Fraud Act must be dismissed.

V. The Premier Defendants cannot be held vicariously liable for the wrongs committed by NECC.

Plaintiffs contend that the Premier Defendants are responsible for the acts of NECC through an exception to the rules of agency in this state, that is to say, Plaintiff argues that Premier hired an incompetent compounding pharmacy. Plaintiffs go through great lengths at pages 25-28 of their brief to outline the various allegations contained within their complaint. However, of the allegations they highlight none speak to the evidence regarding NECC’s incompetence prior to the discovery of the contaminated drugs in October 2012. In fact, the allegations make clear that prior to this date (and prior to the initial interaction with NECC and Premier) there was evidence of warnings generally about compounding pharmacies, publications about compounded drugs in general, and generally Plaintiffs allege that the clinic defendants

knew or should have known that NECC was not accredited and further allege that the clinics should have known that NECC was a wholesale provider. It is not however plead that the Premier Defendants knew or should have known that NECC was an incompetent provider of compounded drugs.

Importantly, Plaintiffs' complaint alleges that "the Clinic Related Defendants manifested assent for NECC to act as their agent and on their behalf when the Clinic Related Defendants Contracted with NECC..." (See plaintiff's complaint at para. 332). The plaintiffs' complaint does not allege at any paragraph that NECC was an independent contractor who was also incompetent and that somehow Premier was aware of their incompetence.

Without pleading appropriately the allegations giving rise to the agency relationship, the claim cannot survive this motion. Specifically, plaintiffs have not plead any fact to show that Premier new or should have known that NECC was an incompetent compounding pharmacy. In addition, the claim for agency as stated in the complaint is one of an assented to agency relationship not one of an Independent Contractor relationship where an exception would apply. No factual basis exists to hold NECC as Premier's Agent in this case.

VI. Plaintiffs have not pled sufficiently a claim for punitive damages must be dismissed.

The PSC responds to the moving defendant's motion to dismiss punitive damages by excerpting paragraphs from the master complaint showing that the words "willfully" and "knowing" were used to describe the conduct of the moving defendants with regard to violations under the New Jersey Consumer Fraud Act (NJCFRA). As explained above, the NJCFRA does not apply to this case. Accordingly, the Consumer Fraud claims must be dismissed and as a result the PSC's master complaint will be void of any allegations of willful or wonton conduct.

CONCLUSION

For these reasons and the reasons expressed in the original motion it is respectfully submitted that the above claim should be dismissed as a matter of law.

Respectfully Submitted,

BLUMBERG & WOLK, LLC
Attorneys for Defendants, Premier Orthopaedic and
Sports Medicine Associates of Southern New Jersey,
LLC, trading as Premier Orthopaedic Associates,
Premier Orthopaedic Associates Surgical Center, LLC,
and Kimberley Yvette Smith, M.D., a/k/a Kimberley
Yvette Smith-Martin, M.D.

Dated: March 21, 2014

By: /s/ Jay J. Blumberg
Jay J. Blumberg, Esq.

CERTIFICATE OF SERVICE

I, Jay J. Blumberg, Esq., hereby certify that I caused a true and correct copy of the response to Opposition by Plaintiffs' Steering Committee to the Motion to Dismiss on behalf of defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, and Kimberley Yvette Smith, M.D., a/k/a Kimberley Yvette Smith-Martin, M.D., to be filed electronically via the Court's electronic filing system.

Dated: March 21, 2014

By: /s/ Jay J. Blumberg
Jay J. Blumberg, Esq.